



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of :

Richard A. SHUMACHER et al.

Group Art Unit: 1626

Serial No.: 10/622,833

Examiner: Rebecca. L. Anderson

Filed: July 21, 2003

For: PHOSPHODIESTERASE 4 INHIBITORS, INCLUDING N-SUBSTITUTED  
ANILINE AND DIPHENYLAMINE ANALOGS

**PETITION OF THE RESTRICTION AND ELECTION OF  
SPECIES REQUIREMENTS UNDER 37 C.F.R. §1.181**

**TECHNOLOGY CENTER 1600**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

This is a petition requesting the Commissioner, through the Honorable Group Director, to reverse the Examiner's decision to maintain the Restriction Requirement, to reverse the finality of the Office Action, and order that examination proceed in accordance with MPEP §803.02.

**Statement of Facts**

**1. Initial Restriction Requirement**

On September 1, 2005, the Examiner issued an Office Action which set forth a Restriction Requirement. Restriction was made between two groups: Group I, drawn to products (claims 1-7, 21, 22, 36, 37, 51, 52, 66, 67, 81, 82, 96, 97, and 111-113); and Group II, drawn to methods of use (claims 8-20, 23-35, 38-50, 53-65, 68-80, 83-95, and 98-110).

Additionally, the Examiner made an election of species requirement, requiring election of a specific single compound, regardless of whether Group I or Group II was elected.

In this first Office Action, the Examiner also cited *In re Harnisch* and *Ex parte Hozumi*, and argued that "restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature ...." The Office Action did not set forth any arguments applying this test to applicants' Markush group.

The Office Action merely asserted that the "Markush group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention." See page 2 of the Office Action. No support was given for this conclusory statement. Further, the Office Action asserted that each Group involved "compounds which are recognized in the art as being distinct from one another because of their diverse chemical structures, their different chemical properties, modes of action, different effects and reactive conditions." See page 5 of the Office Action. Here again, no support was provided for this conclusory statement.

## 2. Election

In response to the Office Action of September 1, 2005, applicants filed an Election on September 22, 2005. Applicants elected Group I and the species *N*-(3-ethoxy-4-methoxyphenyl)-*N*-(3-pyridylmethyl)-4-aminobenzoic acid.

Applicants further stated their understanding was that, upon determination that the elected species is allowable, examination would be extended to other species and further, upon determination that a generic claim is allowable, applicants will be advised that the claims drawn to the non-elected species were no longer withdrawn.. As for the Examiner's comments regarding *In re Harnisch* and *Ex parte Hozumi*, applicants argued that 35 USC §121 does **not** permit restriction within a single claim as citing *In re Weber et al.*, 198 USPQ 328 (1978) except in one specific circumstance. The applicants argued that the involved claims were Markush claims, and that criteria for restriction practice relating to Markush-type are set forth in MPEP §803.02. This section of the MPEP states that: '[s]ince the decisions in *In re Weber*, 580 F.2d

455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention."

3. Office Action of December 20, 2006

In the next Office Action, the Examiner acknowledged applicants' elected species and then argued that, pursuant to the election, a certain scope of subject matter within the compound claims was going to be examined. To the extent compound claims recited subject matter beyond the scope to be examined, these claims were objected to in the Office Action as containing non-elected subject matter. All compound claims were objected to on this basis. Thus, the Examiner effectively presented a Restriction within single claims.

In this Office Action, the Examiner responded to applicants' comments in the Election. The Examiner argued that the Restriction was made under 35 USC 121 which gives the Commissioner authority to restrict examination when the application is directed two or more independent and indistinct inventions.

As to applicants' arguments regarding examination of Markush claims, the Examiner argued that "there has been no rejection made under improper Markush groups so *In re Harnisch* and *Ex parte Hozumi*, cited by applicants, are not relevant." Further, the Examiner asserted that *In re Weber* and *In re Haas* were irrelevant because those cases involved rejections under 35 USC 121, not a restriction.

4. Reply filed October 6, 2006

In response to the Office Action, the applicant filed a reply on October 6, 2006. In the Reply, applicants again reiterated that the restriction practice for Markush claims was set forth in MPEP §803.02, and that the Examiner failed to present any rationale as to why MPEP §803.02 was being ignored in this case.

Further, applicants submitted a copy of a Petition Decision (copy enclosed) issued October 25, 2005 in related application Serial No. 10/361,634. The Examiner in Serial No. '634 similarly sought to impose a restriction within a single claim. Applicants argued that the

Restriction was improper and that examination should proceed in accordance with MPEP §803.02. The Examiner maintained the Restriction, and applicants filed a Petition to the Group Director which was granted. In that Petition Decision, the Group Director refuted the position taken by the Examiner and stated that examination was required to proceed in accordance with MPEP §803.02, as argued by the applicants.

5. Final Office Action issued January 16, 2007

In the Final Office Action issued January 16, 2007, the only remaining issue was the asserted inclusion of non-elected subject matter within the claims, based on the Restriction. The compound claims were objected to on this basis

Regarding the Restriction, the Examiner again argued that the Restriction was made under 35 USC §121 which gives the Commissioner authority to limit examination of an application where two or more independent and distinct inventions are claimed. The Examiner further argued that the Restriction was predicated on the alleged “fact” that the claimed subject matter contains independent and distinct inventions, and that applicants did not submit arguments to the contrary.

**Summary of Argument in Support of Reversal of Denial to Extend the Search**

As noted above, it was the Examiner who first cited *In re Harnisch* and *Ex parte Hozumi*, in the first Office Action. The Examiner argued that based on this case law, “restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature ....” Yet, while acknowledging this case law, the Examiner has never set forth any arguments applying the above-mentioned test to applicants’ Markush group.

Instead, the Examiner argues that Restriction is proper under 35 USC 121 whenever the PTO alleges that a Markush group includes independent and distinct inventions. This is contrary to the case law and the MPEP. Moreover, the allegation that the claimed Markush group includes independent and distinct inventions is merely presented as unsupported conclusory

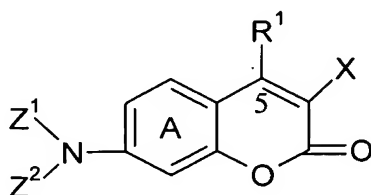
arguments. There is no showing consistent with the Court's interpretation of 35 USC 121 that applicants' Markush group encompasses independent and distinct inventions.

The Examiner argued that Restriction here is predicated on the alleged "fact" that the claimed subject matter contains independent and distinct inventions, and that applicants did not submit arguments to the contrary. Applicants disagree. It is clear that to make a Restriction the burden is on the PTO to set forth a rationale as to why the claimed subject matter contains independent and distinct inventions. MPEP §803.02, in conjunction with the case law, clearly sets forth rationale as to what must be shown to support a Restriction within a single Markush claim. To support a Restriction in such a case, the PTO must show that the Markush grouping is improper. No such showing has been made, and, as acknowledged in the Office Action, no improper Markush rejection has been made. The Examiner has never explained why MPEP §803.02, which cites *In re Harnisch* and *Ex parte Hozumi*, and which clearly sets forth the procedure for examining Markush claims can be ignored in this case.

Further, the Examiner argued that *In re Weber* and *In re Haas* were irrelevant because those cases involved rejections under 35 USC 121, not a restriction. However, this asserted distinction is without merit. In the Restriction imposed here, the Examiner is asserting that the Markush group involves independent and distinct inventions. This is exactly what was being asserted in *Weber* and *Haas*. In *Weber* and *Haas*, the PTO was asserting that applicants were not entitled to have the full scope of their Markush group examined based on the authority given the Commissioner under 35 USC 121. This is exactly what the Examiner is asserting in the instant case. In other words, restriction of subject matter within a Markush-type claim amounts to a rejection for improper Markush grouping.

Clearly, the Examiner, by the Restriction, is refusing to examine that which applicants regard as their invention. This is precisely what the court in *Weber* and *Haas* said was improper, and which the MPEP acknowledges is improper, unless PTO can show that the subject matter in a claim lacks unity of invention, based on the test presented in *Harnisch*.

In *Harnisch*, 206 USPQ 300 (CCPA 1980), the claimed genus of compounds was defined by the following formula:

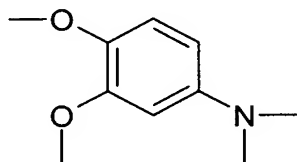


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In this formula,  $Z^1$  was defined as being H, alkyl, cycloalkyl, aralkyl, aryl or a 2- or 3-membered alkylene radical connected to the 6-position of the coumarin ring.  $Z^2$  was defined as being H, alkyl, cycloalkyl, or a 2- or 3-membered alkylene radical connected to the 8-position of the coumarin ring. In addition,  $Z^1$  and  $Z^2$  together with the nitrogen atom could represent an optionally benz-fused heterocyclic ring which "like ring A and the alkyl, aralkyl, cycloalkyl, and aryl radicals mentioned, can carry further radicals customary in dye-stuff chemistry."

Thus, as can be seen, the definition of  $Z^1$  and  $Z^2$  encompassed a very wide variety of structures including various nitrogen containing heterocyclic structures such as morpholinyl, piperidyl, piperazinyl, etc. Yet, the Court in *Harnisch* reversed the improper Markush rejection noting that the claimed compounds were dyes and that the subgenus claimed was not repugnant to scientific classification.

Applicants' Markush groups exhibit the following common core structure:



No rationale is presented in the Office Actions as to why this genus of compounds would be repugnant to scientific classification. Additionally, the compounds are PDE4 inhibitors. Thus, the Markush groupings of applicant's claims are proper and the restriction should be withdrawn.

Moreover, this issue has already been effectively the subject of a Petition **granted** by the Group Director. As discussed in the Reply filed October 6, 2006, a Restriction was made in related application Serial No. 10/361,634 (one of the references used in the instant application as a basis for a rejection under 35 USC 102(e)). **Structural Formula (I) in claim 1 of '634 is the same as structural Formula (I), the difference being in the definitions of the variable groups.** Thus, the core structure in the claims of the instant application is the same as the core structure in '634.

In the Petition Decision, the Group Director refuted the position taken by the Examiner and stated that examination should proceed in accordance with MPEP §803.02, as argued by the applicants.

While the examiner states that the "restriction" requirement is supported by the burden placed on the Office of examining the large Markush group, **such reasoning is improper under M.P.E.P. 803.02.**

A review of claim 1 shows that a substituted benzene ring is claimed. The substituents are two alkoxy groups ortho to each other and an amino group para to one of the alkoxy groups. The four radicals of the three groups are generally alkyl or cyclic alkyl groups, but may involve additional substitution. **However, the various species evidence a common core (the substituted benzene ring) and are alleged to have a utility associated with the core structure thus satisfying the criteria set forth in M.P.E.P. 803.02 for making an election of species requirement. When such a requirement is made, the guidelines of M.P.E.P. 803.02 are required to be followed. Creation of a subgenus based on the elected species is not permitted.** In view of the above, the restriction between original Groups I and II is deemed to be an election of species requirement and the examiner's requirement to limit the claims to a subgenus determined by the examiner is withdrawn. (emphasis added)

The Group Director's decision then instructed the Examiner to follow the guidelines of MPEP 803.02 in examining the application.

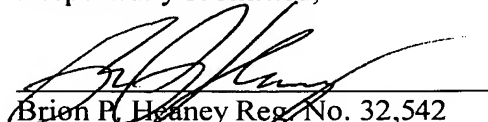
In the Office Action of January 16, 2007, the Examiner acknowledged that applicants directed her attention to this prior Petition Decision, but did not comment directly on the merits of the Decision. The Examiner never refuted the Group Director's reasoning in granting that prior Petition Decision. The Examiner has presented no rationale as to why the Restriction is being maintained in the instant application when it is clearly contrary to the reasoning of the prior Petition Decision.

### **Conclusion**

For the reasons presented above, applicants respectfully request reversal of the Examiner's decisions to maintain the Restriction Requirement, to issue a Final Office Action, and to deny examination of applicants' claims in accordance with MPEP §803.02.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

  
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Attorney Docket No.: **MEMORY-28**

Date: April 2, 2007





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In re Application of	:
Richard A. Schumaker et al	:
Serial No.: 10/361,634	: PETITION DECISION
Filed: February 11, 2003	:
Attorney Docket No.: MEMORY-1 D1	:

This is in response to a second petition under 37 CFR 1.144, filed September 6, 2005, requesting withdrawal of an improper restriction requirement.

## BACKGROUND

A review of the file history was set forth in the previous decision, but is repeated herein for purposes of this decision. The prosecution history shows that this application was filed under 35 U.S.C. 111 on February 11, 2003, and contained claims 1-59. In a first Office action, mailed September 11, 2003, the examiner required restriction between the inventions claimed, as follows:

Group I – Claims 1-19, 25, 31, 37-39 and 41-59 (all in part) drawn to compounds, pharmaceutical compositions and method of treating wherein R1 is an alky (sic alkyl) group, R2 is a cycloalkyl, R3 is an arylalkyl and R4 is an aryl group;

Group II – Claims 1-59 (in part) drawn to compounds, compositions and methods of treating where the definitions are different for R1, R2, R3, R4 than those in Group I.

An election of species was also required for Group II.

The examiner reasoned that the inventions were distinct based on the wide variety of definitions for R1-R4 which give rise to many permutations and combinations and a reference anticipating one species would not anticipate or render obvious another. Very old (and no longer relied upon) case law was cited. The examiner also indicated that a telephone interview with Mr. John Saab had been conducted in which the invention of Group I was elected and the species of compound d, page 66, line 11, elected. No prior art on the species was found and applicants were requested to cancel the non-elected subject matter.

Applicants replied on December 11, 2003, amending a number of claims and adding claims 60-86. Applicants traversed the restriction requirement by arguing that all claims are within the scope of the generic claim and restriction is improper. Applicants argued that the examiner failed to show that the two Groups identified were unrelated or not capable of use together nor why the Groups are not classified together. Further argued was that the division appeared to be arbitrary with no reasons given to justify the division.

The examiner mailed a new Office action to applicants on March 1, 2004, maintaining the restriction requirement maintaining that there was no unity in the core itself. The examiner also argued that merely because they have the same properties they need not necessarily be grouped together. The examiner then added two additional groups to the restriction requirement, restricting Group I to claims 1, 3, 5-6, 8-16, 18, 41-48, 52-56 and 60-86 drawn to compounds, compositions and methods for treating cognition impairment.

Group III was defined as claims 49-51, drawn to other methods of treating.

Group IV was drawn to claim 57 compounds which were indicated as being outside the scope of the compounds of the other claims.

(Note – no Group II was set forth, but is presumed to be as in the first Office action.) The elected claims were indicated as allowable over the prior art.

An interview was held with the examiner on July 22, 2004, but agreement was not reached on all issues.

Applicants filed a formal reply on August 2, 2004, amending claims 18, 41 and 57, and canceling claims 2, 4, 7, 17, 19-40, 50-51 and 58-59. Applicants further traversed the previous and new restriction requirements as improper arguing that the examiner's argument that the core is not novel is in error since there is no requirement that the core be novel, only that the compounds of which the core is a part be novel. Applicants further argued that the examiner's attempts to limit the claims amounted to an improper restriction within a claim or improper rejection. Applicants urged the examiner to follow M.P.E.P. 803.02 in examining a claim in which an election of species has been required.

The examiner mailed a Final Office action to applicants on December 7, 2004, maintaining the withdrawal of claim 57 only. Claims 1, 63-64 (or 68-69) and 83-84 were rejected under 35 U.S.C. 112, first paragraph as lacking enablement, with all other claims being found allowable, but objected to.

Applicants filed a reply to the Office action on March 7, 2005, objecting to the finality of the Office action in view of new rejections made not necessitated by applicants' amendments. Applicants continued the traversal of the restriction requirement, especially with respect to claim 57. Applicants also addressed the rejections of record:

Applicants filed a first petition on March 9, 2005, requesting withdrawal of an improper restriction requirement. A petition decision was mailed to applicants on June 2, 2005, directing the examiner to withdraw the restriction requirement between claim 57 and the other claims to the compounds. It was stated that it appeared that the entire scope of the claims was being

examined as the only objection to the claims appeared to be based on claims depending from a rejected base or independent claim.

Subsequent to the decision the examiner mailed a new Final Office action to applicants on June 3, 2005, in which claim 57 was rejoined with the other claims. However, the examiner then stated that the claims contain non-elected subject matter. All other claim rejections were withdrawn. The examiner advised applicants to amend their claims to the elected scope.

Applicants filed a reply to the Office action and this petition on September 5, 2005. The reply has not been acted on by the examiner.

## DISCUSSION

Applicants petition requests review of the restriction requirement as originally set forth which now appears in view of the examiner's action to not have been withdrawn as stated in the previous petition decision. As noted above, the first Office action divided the claims into two groups following a telephone "election of species" requirement made by the examiner. A review of the manner in which the requirement is set forth shows that what is purported to be a restriction requirement is actually an election of species requirement in which the examiner has examined the species and found it allowable and has expanded the "scope" of the species to create effectively a subgenus of the full genus set forth in the Markush group and limited examination to only the created subgenus. Such is improper. While the examiner states that the "restriction" requirement is supported by the burden placed on the Office of examining the large Markush group, such reasoning is improper under M.P.E.P. 803.02.

A review of claim 1 shows that a substituted benzene is claimed. The substituents are two alkoxy radicals ortho to each other and an amino group para to one of the alkoxy groups. The four radicals of the three groups are generally alkyl or cyclic alkyl groups, but may involve additional substitution. However, the various species evidence a common core (the substituted benzene ring) and are alleged to have a utility associated with the core structure thus satisfying the criteria set forth in M.P.E.P. 803.02 for making an election of species requirement. When such a requirement is made, the guidelines of M.P.E.P. 803.02 are required to be followed. Creation of a subgenus based on the elected species is not permitted. In view of the above, the restriction requirement between original Groups I and II is deemed to be an election of species requirement and the examiner's requirement to limit the claims to the subgenus determined by the examiner is withdrawn.

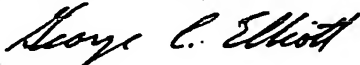
## DECISION

The petition is **GRANTED**.

In view of the above decision, the Finality of the last Office action is withdrawn. Further, the original "restriction" requirement is found to have been an "election of species" requirement for which the guidelines of M.P.E.P. 803.02 must be followed. As applicants have timely replied to the Office action the application will be forwarded to the examiner

**for consideration of applicants' reply and further action commensurate with an election of species requirement of the above decision.**

Should there be any questions about this decision please contact William R. Dixon, Jr., by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0519 or by facsimile sent to the general Office facsimile number.



George C. Elliott  
Director, Technology Center 1600